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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,240	10/21/2005	Zheng Xin Dong	119P/PCT2/US	5791

7590 10/20/2010
Brian R Morrill
Biomeasure, Incorporated
27 Maple Street
Milford, MA 01757

EXAMINER

KOSAR, ANDREW D

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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10/20/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/554,240	Applicant(s) DONG ET AL.	
	Examiner ANDREW D. KOSAR	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-17 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/19/10, 5/28/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments/Arguments

Applicant's amendments and arguments filed July 13, 2010 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Claims 1-8, 10-18, 20-25 are pending in the amendment filed July 13, 2010. Claims 18 and 21-25 remain withdrawn for the reasons of record.

While withdrawn from consideration, it is noted Applicant has amended claim 18 to be "The", where it is an independent claim and should recite "A".

Applicant's amendments to the claims overcome the outstanding art rejections, and new grounds of rejection are necessitated by Applicant's IDS submission under 37 CFR 1.97(c), filed May 28, 2010. The search was not extended unnecessarily to additional species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10-17 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, as amended, recites "Z is a ligand of a biological receptor, an analog thereof or a derivative of said ligand or of said analog selected from the group consisting of somatostatin, LHRH and bombesin". It is unclear whether the "derivative of said ligand or of said analog" is selected from somatostatin, LHRH and bombesin, or whether Z is selected from somatostatin, LHRH and bombesin, or whether the ligand of a biological receptor is selected from

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somatostatin, LHRH and bombesin or analogs or derivatives thereof. Furthermore, it is unclear how one can have derivative of an analog, when the analog is undefined, or an analog of a biological receptor ligand where the ligand is undefined. One would not be reasonably apprised of the metes and bounds of the claim with regards to what is a derivative of an analog.

Claim Rejections - 35 USC § 102

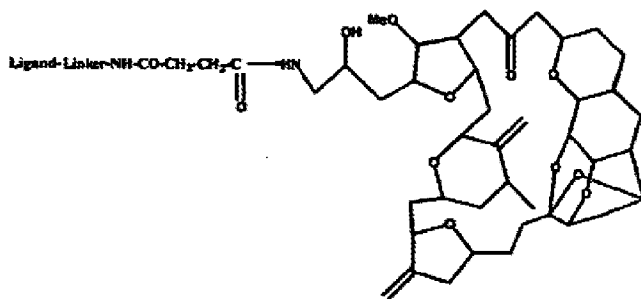
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by TARASOVA (WO 03/072754 A2; IDS 5/28/10).

Tarasova teaches conjugates comprising a ligand, a linker and a cytotoxic agent, where the linker is FALA (e.g. claim 1), the ligand is a peptoid (e.g. claim 3) or a peptide (e.g. claims 4-13) and the cytotoxic agent is ER-86526 (e.g. claim 14) and compositions comprising the conjugate and a carrier (e.g. claim 63). Because there are so few species of cytotoxic agents in claim 14 of Tarasova, each is specifically envisaged. Furthermore, Tarasova further teaches that the derivatives of ER-086526 have the structure (page 30):



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Relative to the instant claims, 'ligand' is Z- a ligand of a biological receptor (in light of the indefiniteness rejection, above), B^1-B^5 is $ALAF-C(O)CH_2CH_2C(O)-$, where A^{2-4} are each absent, $A^{1,5}$ are each CH_2 , B^{2-4} can be parsed in a variety of ways, including B^2 = dipeptide, $B^{3,4}$ = amino acid, and X is a cytotoxic agent, ER-086524.

Information Disclosure Statement

It is noted that a duplicate submission of the IDS of February 19, 2010 was in the file. The second copy has been "not considered" so as to prevent duplicate entries on the front of any patent issued from the application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Additionally, Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on May 28, 2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b) and MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654